
TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Final Rule

LSA Document #05-193(F)

DIGEST

Amends [410 IAC 15-1.1](#) by adding various definitions. Adds [410 IAC 15-1.4-2.2](#) to include serious adverse event reporting in the requirements for a hospital's quality assessment and improvement program. Effective 30 days after filing with the Publisher.

[410 IAC 15-1.1-1](#); [410 IAC 15-1.1-2.5](#); [410 IAC 15-1.1-3.3](#); [410 IAC 15-1.1-3.7](#); [410 IAC 15-1.1-8.5](#); [410 IAC 15-1.1-13.1](#); [410 IAC 15-1.1-13.2](#); [410 IAC 15-1.1-13.3](#); [410 IAC 15-1.1-13.4](#); [410 IAC 15-1.1-13.5](#); [410 IAC 15-1.1-13.6](#); [410 IAC 15-1.1-13.7](#); [410 IAC 15-1.1-14.2](#); [410 IAC 15-1.1-15.5](#); [410 IAC 15-1.1-20](#); [410 IAC 15-1.1-21](#); [410 IAC 15-1.1-22](#); [410 IAC 15-1.1-23](#); [410 IAC 15-1.4-2.2](#)

SECTION 1. [410 IAC 15-1.1-1](#) IS AMENDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-1](#) Applicability

Authority: [IC 16-21-1-7](#); [IC 16-21-1-8](#); [IC 16-21-1-9](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 1. The definitions in this rule apply throughout this article **except as otherwise indicated**.

(Indiana State Department of Health; [410 IAC 15-1.1-1](#); filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; filed Nov 16, 2006, 4:01 p.m.: [20061213-IR-410050193FRA](#))

SECTION 2. [410 IAC 15-1.1-2.5](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-2.5](#) "ASA class 1 patient" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 2.5. "ASA class 1 patient" means a normal, healthy patient.

(Indiana State Department of Health; [410 IAC 15-1.1-2.5](#); filed Nov 16, 2006, 4:01 p.m.: [20061213-IR-410050193FRA](#))

SECTION 3. [410 IAC 15-1.1-3.3](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-3.3](#) "Biologics" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 3.3. "Biologics" means a biological product, such as:

- (1) a globulin;
- (2) a serum;
- (3) a vaccine;
- (4) an antitoxin;
- (5) blood; or
- (6) an antigen;

used in the prevention or treatment of disease.

(Indiana State Department of Health; [410 IAC 15-1.1-3.3](#); filed Nov 16, 2006, 4:01 p.m.: [20061213-IR-410050193FRA](#))

SECTION 4. [410 IAC 15-1.1-3.7](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-3.7](#) "Burn" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 3.7. "Burn" means any injury or damage to the tissues of the body caused by exposure to any of the following:

- (1) Fire.
- (2) Heat.
- (3) Chemicals.
- (4) Electricity.
- (5) Radiation.
- (6) Gases.

(Indiana State Department of Health; [410 IAC 15-1.1-3.7](#); filed Nov 16, 2006, 4:01 p.m.:
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SECTION 5. [410 IAC 15-1.1-8.5](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-8.5](#) "Elopement" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 8.5. "Elopement" means any situation in which a registered or admitted patient, excluding events involving adults with decision making capacity, leaves the hospital without staff being aware that the patient has done so.

(Indiana State Department of Health; [410 IAC 15-1.1-8.5](#); filed Nov 16, 2006, 4:01 p.m.:
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SECTION 6. [410 IAC 15-1.1-13.1](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-13.1](#) "Hyperbilirubinemia" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 13.1. "Hyperbilirubinemia" means total serum bilirubin levels greater than twenty-five (25) mg/dl in a neonate.

(Indiana State Department of Health; [410 IAC 15-1.1-13.1](#); filed Nov 16, 2006, 4:01 p.m.:
[20061213-IR-410050193FRA](#))

SECTION 7. [410 IAC 15-1.1-13.2](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-13.2](#) "Hypoglycemia" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 13.2. "Hypoglycemia" means a physiologic state in which:

- (1) the blood sugar falls below sixty (60) mg/dl (forty (40) mg/dl in neonates); and
- (2) physiological or neurological, or both, dysfunction begins.

(Indiana State Department of Health; [410 IAC 15-1.1-13.2](#); filed Nov 16, 2006, 4:01 p.m.:
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SECTION 8. [410 IAC 15-1.1-13.3](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-13.3](#) "Immediately postoperative" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 13.3. "Immediately postoperative" means within twenty-four (24) hours after either of the following:

- (1) Induction of anesthesia (if surgery or other invasive procedure is not completed).**
- (2) Completion of surgery or other invasive procedure.**

(Indiana State Department of Health; [410 IAC 15-1.1-13.3](#); filed Nov 16, 2006, 4:01 p.m.:
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SECTION 9. [410 IAC 15-1.1-13.4](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-13.4](#) "Informed consent" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 13.4. "Informed consent" means a patient's authorization or agreement to undergo surgery or other invasive procedure that is based upon communication between a patient and his or her physician regarding such surgery or other invasive procedure.

(Indiana State Department of Health; [410 IAC 15-1.1-13.4](#); filed Nov 16, 2006, 4:01 p.m.:
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SECTION 10. [410 IAC 15-1.1-13.5](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-13.5](#) "Intended use" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 13.5. "Intended use" means the use of a device as described on the label and associated materials provided by the device's manufacturer.

(Indiana State Department of Health; [410 IAC 15-1.1-13.5](#); filed Nov 16, 2006, 4:01 p.m.:
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SECTION 11. [410 IAC 15-1.1-13.6](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-13.6](#) "Joint movement therapy" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 13.6. "Joint movement therapy" means all types of manual techniques, to include:

- (1) mobilization (movement of the spine or a joint within its physiologic range of motion);**
- (2) manipulation (movement of the spine or a joint beyond its normal voluntary physiologic range of**

motion); or

(3) any other type of manual musculoskeletal therapy;
regardless of their precise anatomic and physiologic focus or their discipline of origin.

(Indiana State Department of Health; [410 IAC 15-1.1-13.6](#); filed Nov 16, 2006, 4:01 p.m.:
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SECTION 12. [410 IAC 15-1.1-13.7](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-13.7](#) "Kernicterus" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 13.7. "Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage.

(Indiana State Department of Health; [410 IAC 15-1.1-13.7](#); filed Nov 16, 2006, 4:01 p.m.:
[20061213-IR-410050193FRA](#))

SECTION 13. [410 IAC 15-1.1-14.2](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-14.2](#) "Low-risk pregnancy" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 14.2. "Low-risk pregnancy" means a woman sixteen (16) to thirty-nine (39) years of age with no previous diagnosis of any of the following:

- (1) Essential hypertension.
- (2) Renal disease.
- (3) Collagen-vascular disease.
- (4) Liver disease.
- (5) Preeclampsia.
- (6) Cardiovascular disease.
- (7) Placenta previa.
- (8) Multiple gestation.
- (9) Intrauterine growth retardation.
- (10) Smoking.
- (11) Pregnancy-induced hypertension.
- (12) Premature rupture of membranes.
- (13) Other previously documented condition that poses a high risk of pregnancy-related mortality.

(Indiana State Department of Health; [410 IAC 15-1.1-14.2](#); filed Nov 16, 2006, 4:01 p.m.:
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SECTION 14. [410 IAC 15-1.1-15.5](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-15.5](#) "Neonates" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 15.5. "Neonates" means infants in the first twenty-eight (28) days of life.

(Indiana State Department of Health; [410 IAC 15-1.1-15.5](#); filed Nov 16, 2006, 4:01 p.m.:
[20061213-IR-410050193FRA](#))

SECTION 15. [410 IAC 15-1.1-20](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-20](#) "Serious disability" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 20. "Serious disability" means either of the following:

- (1) Significant loss of function including sensory, motor, physiologic, or intellectual impairment:**
 - (A) not present on admission and requiring continued treatment; or**
 - (B) for which there is a high probability of long term or permanent lifestyle change at discharge.**
- (2) Unintended loss of a body part.**

*(Indiana State Department of Health; [410 IAC 15-1.1-20](#); filed Nov 16, 2006, 4:01 p.m.:
[20061213-IR-410050193FRA](#))*

SECTION 16. [410 IAC 15-1.1-21](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-21](#) "Sexual assault" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#); [IC 35-42-4](#); [IC 35-46-1-3](#)

Sec. 21. "Sexual assault" means a crime included under [IC 35-42-4](#) or [IC 35-46-1-3](#).

*(Indiana State Department of Health; [410 IAC 15-1.1-21](#); filed Nov 16, 2006, 4:01 p.m.:
[20061213-IR-410050193FRA](#))*

SECTION 17. [410 IAC 15-1.1-22](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-22](#) "Surgery or other invasive procedure" defined

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 22. For purposes of this rule, [410 IAC 15-1.4-2.2](#), and [410 IAC 15-2.4-2.2](#) [sic.], "surgery or other invasive procedure" means surgical or other invasive procedures that involves [sic., involve] a skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure begins at the time of the skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. Such procedures include, but are not limited to:

- (1) Open or percutaneous surgical procedures.**
- (2) Percutaneous aspiration.**
- (3) Selected injections.**
- (4) Biopsy.**
- (5) Percutaneous cardiac and vascular diagnostic or interventional procedures.**
- (6) Laparoscopies.**
- (7) Endoscopies.**
- (8) Colonoscopies.**

The term excludes intravenous therapy, venipuncture for phlebotomy, diagnostic tests without intravenous contrast agents, nasogastric tubes, or indwelling urinary catheters.

*(Indiana State Department of Health; [410 IAC 15-1.1-22](#); filed Nov 16, 2006, 4:01 p.m.:
[20061213-IR-410050193FRA](#))*

SECTION 18. [410 IAC 15-1.1-23](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.1-23](#) "Toxic substance" defined

Sec. 23. "Toxic substance" means chemicals that are present in sufficient concentration to pose a hazard to human health.

*(Indiana State Department of Health; [410 IAC 15-1.1-23](#); filed Nov 16, 2006, 4:01 p.m.:
[20061213-IR-410050193FRA](#))*

SECTION 19. [410 IAC 15-1.4-2.2](#) IS ADDED TO READ AS FOLLOWS:

[410 IAC 15-1.4-2.2](#) Reporting serious adverse events

Authority: [IC 16-19-3-4](#); [IC 16-21-1-7](#)

Affected: [IC 16-19-3](#); [IC 16-21-1](#)

Sec. 2.2. (a) The hospital's quality assessment and improvement program under section 2 of this rule shall include the following:

(1) A process for determining the occurrence of the following serious adverse events within the hospital:

(A) The following surgical events:

(i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;

or both.

(ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.

(iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;

or both.

(iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:

(AA) Objects intentionally implanted as part of a planned intervention.

(BB) Objects present before surgery that were intentionally retained.

(CC) Retention of broken microneedles.

(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.

(B) The following product or device events:

(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the hospital. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.

(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:

(AA) Catheters.

(BB) Drains and other specialized tubes.

(CC) Infusion pumps.

(DD) Ventilators.

(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the hospital. Excluded are deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(C) The following patient protection events:

(i) Infant discharged to the wrong person.

(ii) Patient death or serious disability associated with patient elopement.

(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the hospital, defined as events that result from patient actions after admission to the hospital.

Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the hospital.

(D) The following care management events:

(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:

(AA) drug;

(BB) dose;

(CC) patient;

(DD) time;

(EE) rate;

(FF) preparation; or

(GG) route of administration.

Excluded are reasonable differences in clinical judgment on drug selection and dose.

(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the hospital. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:

(AA) Pulmonary or amniotic fluid embolism.

(BB) Acute fatty liver of pregnancy.

(CC) Cardiomyopathy.

(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the hospital.

(v) Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates.

(vi) Stage 3 or 4 pressure ulcers acquired after admission to the hospital. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable due to the presence of eschar.

(vii) Patient death or serious disability due to joint movement therapy performed in the hospital.

(E) The following environmental events:

(i) Patient death or serious disability associated with an electric shock while being cared for in the hospital. Excludes events involving planned treatment, such as electrical countershock.

(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:

(AA) contains the wrong gas; or

(BB) is contaminated by toxic substances.

(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the hospital.

(iv) Patient death associated with a fall while being cared for in the hospital.

(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the hospital.

(F) The following criminal events:

(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.

(ii) Abduction of a patient of any age.

(iii) Sexual assault on a patient within or on the grounds of the hospital.

(iv) Death or significant injury of a patient or staff member resulting from a physical assault, that is, battery, that occurs within or on the grounds of the hospital.

(2) A process for reporting to the department each serious adverse event listed in subdivision (1) that is determined by the hospital's quality assessment and improvement program to have occurred within the hospital.

(b) Subject to subsection (e), the process for determining the occurrence of the serious adverse events listed in subsection (a)(1) by the hospital's quality assessment and improvement program shall be designed by the hospital to accurately determine the occurrence of any of the serious adverse events listed in subsection (a)(1) within the hospital in a timely manner.

(c) Subject to subsection (e), the process for reporting the occurrence of a serious adverse event

listed in subsection (a)(1) shall comply with the following:

(1) The report shall:

- (A) be made to the department;
- (B) be submitted not later than fifteen (15) working days after the serious adverse event is determined to have occurred by the hospital's quality assessment and improvement program;
- (C) be submitted not later than six (6) months after the potential event is brought to the program's attention; and
- (D) identify the serious adverse event and the hospital, but shall not include any identifying information for any:
 - (i) patient;
 - (ii) individual licensed under [IC 25](#); or
 - (iii) hospital employee involved;or any other information.

(2) A potentially reportable serious adverse event may be identified by a hospital that receives a patient as a transfer from another health care facility subject to a serious adverse event requirement or admits a patient subsequent to discharge from another health care facility subject to a serious adverse event requirement. In the event that a hospital identifies a potentially reportable event originating from another health care facility subject to a serious adverse event requirement, the identifying hospital shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a serious adverse reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(d) The hospital's report of a serious adverse event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of such serious adverse events occurring within each hospital. The department's public report will be issued no less frequently than annually.

(e) Any serious adverse event listed in subsection (a)(1), that:

(1) is determined to have occurred within the hospital between:

- (A) January 1, 2006; and
- (B) the effective date of this rule; and

(2) has not been previously reported;

must be reported within five (5) days of the effective date of this rule.

(Indiana State Department of Health; [410 IAC 15-1.4-2.2](#); filed Nov 16, 2006, 4:01 p.m.: [20061213-IR-410050193FRA](#))

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